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(71) Applicant: UROLOGIX, INC. [US/US]; 14405 21st Avenue North, Minneapolis, MN 55447 (US).

(72) Inventor: THOMPSON, Barry M.; 6258 Fernbrook Lane, Maple Grove, MN 55311 (US).

(74) Agents: FAIRBAIRN, David, R. et al.; Kinney & Lange, P.A., Suite 1500, 625 4th Avenue South, Minneapolis, MN 55415-1659 (US).

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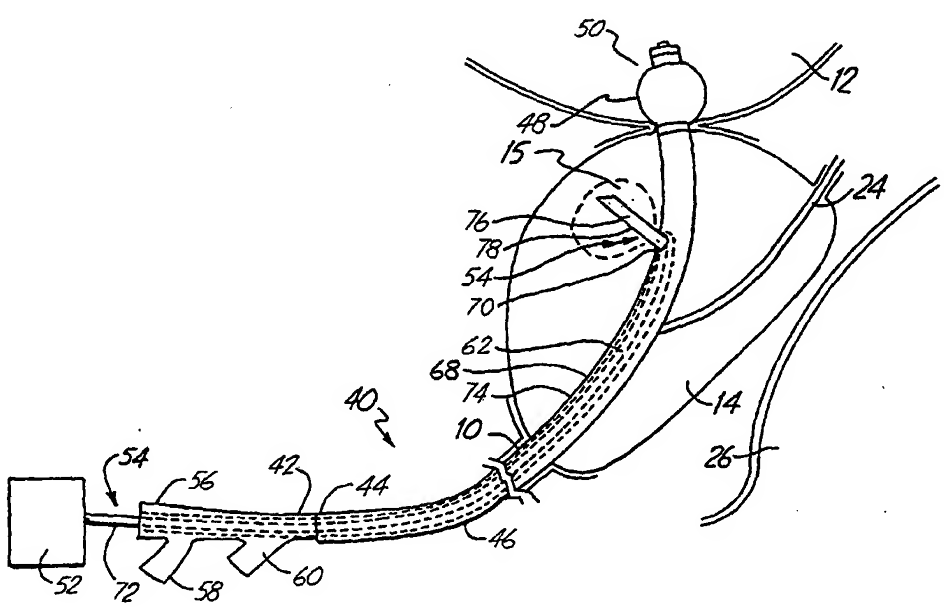

(57) Abstract

A urethral catheter (40) includes a passageway (62) for a radiating element (86). The passageway (62) is exposed through a sidewall (68) of the catheter (40) to permit the radiating element (86) to exit the catheter (40) and enter prostate tissue (14) at a preselected location. Electromagnetic energy supplied to the radiating element (86) causes localized heating of the prostate tissue (14) which surrounds the radiating element (86).

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PIERCING THERMAL THERAPY CATHETER

BACKGROUND OF THE INVENTION

The present invention relates to the field of thermal therapy of tissue. In particular, the present invention relates to a catheter for transurethral thermal therapy of benign prostatic hyperplasia (BPH).

The prostate gland is a complex, chestnut-shaped organ which encircles the urethra immediately below the bladder. Nearly one third of the prostate tissue anterior to the urethra consists of fibromuscular tissue that is anatomically and functionally related to the urethra and bladder. The remaining two thirds of the prostate is generally posterior to the urethra and is comprised of glandular tissue.

This relatively small organ, which is the most frequently diseased of all internal organs, is the site of a common affliction among older men: BPH (benign prostatic hyperplasia). BPH is a nonmalignant, bilateral nodular expansion of prostrate tissue in the transition zone, a periurethral region of the prostate between the fibromuscular tissue and the glandular tissue. The degree of nodular expansion within the transition zone tends to be greatest anterior and lateral to the urethra, relative to the posterior-most region of the urethra. Left untreated, BPH causes obstruction of the urethra which usually results in increased urinary frequency, urgency, incontinence, nocturia and slow or interrupted urinary stream. BPH may also result in more severe complications, such as urinary tract infection, acute urinary retention, hydronephrosis and uraemia.

Traditionally, the most frequent treatment for BPH has been surgery (transurethral resection). Surgery, however, is often not an available method of treatment for a variety of reasons. First, due to the advanced age of many patients with BPH, other health problems, such as cardiovascular disease, can warrant against surgical intervention. Second, potential complications associated with transurethral surgery, such as hemorrhage,

anesthetic complications, urinary infection, dysuria, incontinence and retrograde ejaculation, can adversely affect a patient's willingness to undergo such a procedure.

A fairly recent alternative treatment method for BPH involves microwave thermal therapy, in which microwave energy is employed to elevate the temperature of tissue surrounding the prostatic urethra above about 45°C, thereby thermally damaging the tumorous tissue. Delivery of microwave energy to tumorous prostatic tissue is generally accomplished by a microwave antenna-containing applicator, which is positioned within a body cavity adjacent the prostate gland. The microwave antenna, when energized, heats adjacent tissue due to molecular excitation and generates a cylindrically symmetrical radiation pattern which encompasses and necroses the tumorous prostatic tissue. The necrosed intraprostatic tissue is subsequently reabsorbed by the body, thereby relieving an individual from the symptoms of BPH.

One method of microwave thermal therapy described in the art includes intrarectal insertion of a microwave antenna-containing applicator. Heat generated by the antenna's electromagnetic field is monitored by a sensor which is positioned near the prostate gland by a urethral catheter. Owing to the distance between the rectum and the tumorous prostatic tissue of the transition zone, however, healthy intervening tissue within the cylindrically symmetrical radiation pattern is also damaged in the course of the intrarectal treatment. Intrarectal microwave thermal therapy applicators are described in the following references: Eshel et al. U.S. Patent 4,813,429; and, A. Yerushalmi et al., Localized Deep Microwave Hyperthermia in the Treatment of Poor Operative Risk Patients with Benign Prostatic Hyperplasia, 133 JOURNAL OF UROLOGY 873 (1985).

A safer and more efficacious treatment of BPH is transurethral microwave thermal therapy. This method of treatment minimizes the

distance between a microwave antenna-containing applicator and the transition zone of the prostate by positioning a Foley-type catheter-bearing applicator adjacent to the prostate gland within the urethra. Due to the close proximity of the microwave antenna to the prostate, a lesser volume of tissue is exposed to the cylindrically symmetrical radiation pattern generated by the microwave antenna, and the amount of healthy tissue necrosed is reduced. Intraurethral applicators of the type described can be found in Turner et al., U.S. Patent 4,967,765 and Hascoet et al., European Patent Application 89403199.6.

While the close proximity of a transurethral microwave thermal therapy applicator to prostatic tissue reduces the amount of damage to healthy tissue, controlling the volume of tissue to be affected by the microwave energy field continues to be problematic. For instance, microwave antennas known in the art have tended to produce electromagnetic fields which affect a volume of tissue, beyond the desired area of treatment, which necroses healthy, normal tissue.

SUMMARY OF THE INVENTION

The present invention is based upon the recognition that in patients suffering from BPH, tumorous tissue growth within the prostate tends to be the greatest in the portion of the transition zone anterior and lateral to the urethra. The present invention is a transurethral thermal therapy catheter for thermal treatment of BPH which is capable of selectively directing energy toward tumorous prostatic tissue growth anterior and lateral to the urethra, while sparing the urethra and healthy tissue posterior to the urethra from thermal damage. The energy is directed by placing an energy emitter within the targeted tissue instead of within the urethra or rectal cavity.

The catheter preferably includes a flexible shaft which contains at least one lumen that extends from the base of the catheter to an opening

along the length of the catheter. The catheter is placed within a urethra so that the opening along the length of the catheter is near the targeted tissue. An energy emitter is fed through the lumen of the catheter from the base. The emitter is shaped so that it can slice through tissue surrounding the catheter as it is inserted past the opening along the length of the catheter. Once inside the targeted tissue, the energy emitter is activated and emits energy which heats the tissue surrounding the energy emitter. This affectively necroses the heated tissue. Because the emitter is placed closer to the tumorous prostatic tissue than prior art emitters, it is able to necrose tumorous tissue while affecting lower quantities of heathy tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a vertical sectional view of a male pelvic region showing the urinary organs affected by benign prostatic hyperplasia.

Fig. 2 is an enlarged side view of the male pelvic region of Fig. 1 showing the urethral catheter of the present invention positioned within the prostate region.

Fig. 2A is a cross-sectional view of flexible shaft 46 of Fig. 2.

Fig. 3 is an enlarged front sectional view of a fragmentary portion of the catheter of the present invention.

Fig. 4 is a front sectional view of the male pelvic region of Fig. 1 showing a second embodiment of the catheter of the present invention positioned within the prostate region.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Fig. 1 is a vertical sectional view of a male pelvic region showing the effect benign prostatic hyperplasia (BPH) has on the urinary organs. Urethra 10 is a duct leading from bladder 12, through prostate 14 and out orifice 16 of penis end 18. Benign tumorous tissue growth within prostate 14 around urethra 10 causes constriction 20 of urethra 10, which restricts the flow of urine from bladder 12 to orifice 16. The tumorous tissue of prostate 14 which encroaches urethra 10 and causes constriction 20 can be effectively removed by heating and necrosing the encroaching tumorous tissue. Ideally, with the present invention, only periurethral tumorous tissue of prostate 14 anterior and lateral to urethra 10 is heated and necrosed to avoid unnecessary and undesirous damage to urethra 10 and to adjacent healthy tissues, such as ejaculatory duct 24 and rectum 26. A selective heating of benign tumorous tissue of prostate 14 (transurethral thermal therapy) is made possible by energy emitter-containing catheter 48 of the present invention, which is shown in Figs. 2, 2A, 3, and 4.

Fig. 2 is an enlarged view of the male pelvic region of Fig. 1 showing catheter 40 of the present invention positioned within the prostate 14. Catheter 40 is a multilumen Foley-type urethral catheter well known in the art which is extruded from a flexible medical grade silicone sold by Dow Corning under the trademark Silastic Q-7-4850.

Catheter 40 generally comprises manifold 42, distal end 44, flexible shaft 46, balloon 48, proximal end 50, energy source 52, and energy delivery system 54. Catheter 40 has a length sufficient to permit proximal end 50 to be inserted into urethra 10 and positioned within bladder 12 while manifold 42 remains exterior to penis end 18.

Manifold 42 comprises energy emitter port 56, drainage port 58, and balloon inflation port 60. Manifold 42 is connected to flexible shaft 46 at distal end 44. This connection allows energy emitter port 56, drainage

port 58, and balloon inflation port 60 to communicate with corresponding lumens within flexible shaft 46.

These lumens are shown in Fig. 2A which is a cross sectional view of flexible shaft 46. They include aperture lumen 62 which communicates with energy emitter port 56, drainage lumen 64 which communicates with drainage port 58, and balloon inflation lumen 66 which communicates with balloon inflation port 60.

Aperture lumen 62, shown in both Fig. 2 and Fig. 2A, is located midway between a lateral position and an anterior position within flexible shaft 46. Aperture lumen 62 and energy emitter port 56 provide a passageway from a location external to manifold 42 to an aperture located along flexible shaft 46. This passageway guides energy delivery system 54 to a location in urethra 10 near tissue targeted for treatment. In other preferred embodiments, aperture lumen 62 is in one of several positions spanning from one lateral position to the other across the anterior of flexible shaft 46.

Drainage lumen 64 of Fig. 2A is located generally in the center of flexible shaft 46 and extends from drainage port 58 to an opening at proximal end 50. Together with drainage port 58, drainage lumen 64 permits the drainage of urine from bladder 12 when catheter 40 is properly positioned within urethra 10.

Balloon inflation lumen 66 of Fig. 2A is located in a posterior position within flexible shaft 46 and extends from balloon inflation port 60 to the interior of balloon 48. Balloon inflation port 60 is provided to receive an inflation device (not shown) for inflating balloon 48 when balloon 48 is positioned within bladder 12, and for deflating balloon 48 when catheter 40 is to be removed from urethra 10. Balloon inflation lumen 66 provides a passageway for the movement of gas between balloon inflation port 60 and the interior of balloon 48.

In addition to aperture lumen 62, drainage lumen 64 and balloon inflation lumen 66, flexible shaft 46 further comprises outer surface 68, and aperture 70 shown in Fig. 2. Outer surface 68 is a smooth surface which is flexible and strong to permit insertion of flexible shaft 46 into urethra 10. In one preferred embodiment, outer surface 68 is coated with a hydrophilic solution sold by Hydromer, Inc. under the mark Hydromer. Hydromer lubricates outer surface 68 and facilitates the advancement of flexible shaft 60 within urethra 10. Aperture 70 exposes aperture lumen 62 at a location along the length of flexible shaft 46 which generally corresponds with a region of prostate 14 requiring treatment.

Balloon 48 is located near proximal end 50 of catheter 40 and is appurtenant to catheter 40. When inflated within bladder 12, balloon 48 anchors catheter 40 and thereby prevents catheter 40 from changing position in urethra 10 during treatment of prostate 14. Balloon 48 also serves to locate aperture 70 of flexible shaft 46 in the region of prostate 14 requiring treatment.

Energy source 52 is external to manifold 42 and is one of several types of energy sources capable of creating an electrical current and voltage. The current and voltage is alternating or direct.

Energy delivery system 54 comprises a distal portion 72, a middle portion 74, and a proximal portion 76. Distal portion 72 is external to energy emitter port 56 and is coupled to energy source 52. Middle portion 74 is connected to distal portion 72 and extends from energy emitter port 56, through aperture lumen 62, to aperture 70. Proximal portion 76 is connected to middle portion 74 and extends from aperture 70 into prostate tissue 14. All three portions of the energy delivery system have an outer shell 78 which is flexible enough to bend with flexible shaft 46 yet strong enough to support piercing prostate tissue 14.

In operation, proximal end 50 of catheter 40 is introduced into urethra 10 via orifice 16 of penis end 18 of Fig. 1. Proximal end 50 is advanced into bladder 12 through urethra 10 under a longitudinal force applied to flexible shaft 46. Once balloon 48 has reached bladder 12, it is inflated via balloon inflation port 60 and balloon inflation lumen 66. The inflation of balloon 48 secures flexible shaft 46 within urethra 10 so that flexible shaft 46 does not recede from bladder 12.

Proximal portion 76 of energy delivery system 80 is then inserted into aperture lumen 62 via energy emitter port 56 of manifold 42. Proximal end 76 advances along aperture lumen 62 toward aperture 70 through the application of a longitudinal force applied to middle portion 74 and distal portion 72. When proximal portion 76 reaches aperture 70, it pierces tissue surrounding aperture 70 in a manner discussed below. Proximal portion 76 continues to pierce tissue as long as a longitudinal force is applied to middle portion 74 and distal portion 72.

In a preferred embodiment, aperture 70 is located on flexible shaft 46 such that when catheter 40 is anchored in urethra 10, aperture 70 is located near a target tissue 15. When proximal portion 76 is forced into the tissue surrounding aperture 70, it passes into target tissue 15. Once part of proximal portion 76 is within target tissue 15, energy source 52 is activated causing tissue surrounding proximal portion 76 to necrose in a manner described below.

After the tissue has been necrosed, proximal portion 76 is withdrawn from target tissue 15 by withdrawing distal portion 72 and middle portion 74 from energy emitter port 56. Once energy delivery system 80 is completely withdrawn from manifold 42, balloon 48 is deflated via balloon inflation port 60 and balloon inflation lumen 66. Proximal end 50 of catheter 40 is then withdrawn from bladder 12 and urethra 10 past penis end 18 of Fig. 1.

Fig. 3 is an enlarged front sectional view of a fragmentary portion of catheter 40 of the present invention. This section of catheter 40 comprises aperture lumen 62, outer surface 68, aperture 70, parallel guide 80, angled guide 82, and middle portion 74 and proximal portion 76 of energy delivery system 54.

Aperture lumen 62 and parallel guide 80 begin at energy emitter port 56 of Fig. 2. Parallel guide 80 encases aperture lumen 62 and provides a guideway for proximal portion 76 and middle portion 74 of energy delivery system 54. Within the guideway, proximal portion 76 and middle portion 74 travel parallel to outer surface 68.

Angled guide 82 is connected to parallel guide 80 and outer surface 68. It further encases aperture lumen 62. Angled guide 80 is at an angle to outer surface 68 and thus provides an angled guideway for proximal portion 76 and middle portion 74 of energy delivery system 54. Along the guideway, proximal portion 76 and middle portion 74 travel at an angle to outer surface 68.

Aperture 70 is an opening in outer surface 68 created by the intersection of aperture lumen 62 and outer surface 68. Aperture 70 creates an opening from aperture lumen 62 to the surrounding tissue so that proximal portion 76 of energy delivery system 54 may enter surrounding tissue.

Proximal portion 76 of energy delivery system 54 is comprised of outer shell 78, signal carriers 84, inner radiator 86, and piercing tip 88. Outer shell 78 is in contact with angled guide 82 and prostate 14 of Fig. 2. In addition, outer shell 78 encases signal carriers 84 and inner radiator 86. The material composition of outer shell 78 allows it to flex at the junction of parallel guide 80 and angled guide 82 and still provide support to piercing tip 88 as the tip pierces tissue.

Signal carriers 84 are encased in outer shell 78 and are connected to inner radiator 86. Signal carriers 84 extend through proximal portion 76, middle portion 74, and distal portion 72 and are coupled to energy source 52. Signal carriers 84 carry a signal from energy source 52 to inner radiator 86 which causes inner radiator 86 to radiate energy. Inner radiator 86 is encased by outer shell 78 near piercing tip 88. Inner radiator 86 radiates energy in response to signals it receives from signal carriers 84.

Inner radiator 86 may be comprised of a resistive element or a microwave band electromagnetic wave emitter. In one embodiment, inner radiator 86 is the same as the radiator found in the Cook UH8500 hyperthermia catheter manufactured by Cook Incorporated of Bloomington, Indiana. The radiator of the UH8500 hyperthermia catheter utilizes a microwave antenna to emit microwave band electromagnetic radiation into surrounding tissue. In addition, other energy emitters may be used without departing from the spirit and scope of the present invention.

Piercing tip 88 is appurtenant to outer shell 78 on the proximal edge of energy delivery system 54. Piercing tip 88 has a sharp point or edge which is able to pierce tissue.

When proximal portion 76 is passed through aperture lumen 62 from energy emitter port 56, it travels along the length of aperture lumen 62 parallel to outer surface 68 until it reaches angled guide 82. Upon reaching angled guide 82 it is bent at an angle to outer surface 68. It moves at an angle to outer surface 68 toward a portion of urethra 10 at aperture 70. Piercing tip 88 pierces urethra 10 and prostate 14 of Fig. 2 when it exits aperture 70. Once inner radiator 86 is within target tissue 15 of Fig. 2, energy source 52 of Fig. 2 is activated. This sends a signal along signal carriers 84. The signal is received by inner radiator 86 and causes it to radiate energy which heats target tissue 15 of Fig. 2. This necroses target tissue 15 without affecting other tissue of prostate 14 of Fig. 2.

Once target tissue 15 is necrosed, energy source 52 is deactivated causing inner radiator 86 to stop radiating energy. Proximal portion 76 is then withdrawn from target tissue 15 and recedes into aperture lumen 62. Proximal portion 76 travels along angled guide 82 and then parallel guide 80 until it is completely removed from catheter 40.

Fig. 4 is a front sectional view of the male pelvic region of Fig. 1. Fig. 4 shows the proximal portion of a second embodiment of catheter 40 of the present invention positioned within the prostate region. Urethra 10 leads from bladder 12 through prostate 14 as in Fig. 1. In addition, urethra 10 comprises urethra wall 11 and urethra cavity 13. Prostate 14 comprises target tissue 15 and 115 and non-target tissue 17 and 117.

The proximal portion of this second embodiment of catheter 40 generally includes anchor balloon 120, energy delivery systems 122 and 124, and lumen 126 and 128. Catheter 40 passes through urethra cavity 13 and into bladder 12. At the proximal end of catheter 40, anchor balloon 120 anchors catheter 40 so that it does not move within urethra cavity 13.

Energy delivery systems 120 and 124 reside in target tissue 15 and 115 of prostate 14 having pierced urethra wall 11. Energy delivery systems 120 and 124 pierced urethra wall 11 after passing through lumen 126 and 128 respectively. Energy delivery systems 122 and 124 produce heating energy 130 and 132. Heating energy 130 and 132 produce heat in target tissue 15 and 115 respectively but not in non-target tissue 17 and 117. Thus, the heat is localized around target tissue 15 and 115.

As seen above, the present invention allows tumorous tissue of the prostate to be removed by placing an energy emitter directly within the prostate tissue itself. The energy emitter is introduced into the tissue by passing it via an intracavital catheter shaft which guides the en-rgy emitter toward the cavity wall. The energy emitter pierces the cavity wall and enters the surrounding tissue through a force applied to the base of the

energy emitter. Once within the tissue, the energy emitter is activated and begins to necrose surrounding tissue.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

CLAIMS :

1. An apparatus for producing localized heating in periurethral tissue of a prostate, the apparatus comprising:

a urethral catheter having a side wall which defines an outer surface, a first outer surface region and a second outer surface region, the first outer surface region corresponding to an anterior region of the prostate when the catheter is positioned within a urethra, the second outer surface region corresponding to a lateral region of the prostate when the catheter is positioned within the urethra, the catheter further having a distal end, a proximal end for insertion into a bladder, and a lumen extending therebetween, the side wall near the proximal end defining an aperture in communication with the lumen, the aperture being positioned between the first outer surface region and the second outer surface region;

an energy emitting element positionable within the first lumen and capable of exiting the aperture and being inserted into the adjacent periurethral tissue when the catheter is positioned within the urethra; and

an electrical power source communicating with the energy emitting element.

2. The apparatus of claim 1 and further comprising:

a balloon connected to the catheter at the proximal end; and

means for inflating the balloon.

3. The apparatus of claim 1 wherein the energy emitting element comprises a microwave antenna.

4. The apparatus of claim 1 wherein the energy emitting element comprises a resistive element.

5. The apparatus of claim 1 wherein the energy emitting element comprises a piercing tip.

6. A device for delivering localized heat to a prostate, the device comprising:

A catheter having a side wall which defines an outer surface, a proximal end for insertion into a urethra to a bladder, and a distal end;

a balloon connected to the catheter at the proximal end;

means within the catheter for inflating the balloon;

a guiding pathway within the catheter and extending from the distal end toward the proximal end, the side wall of the catheter defining an opening in communication with the pathway near the proximal end in a region of the catheter which corresponds to the prostate when the balloon is within the bladder;

an energy emitting device configured for piercing tissue, the energy emitting device positionable within the pathway and capable of exiting the opening and passing into the prostate when the catheter is in the urethra with the balloon within the bladder; and

an electrical power source communicating with the energy emitting device.

7. The apparatus of claim 6 wherein the energy emitting element comprises a microwave antenna.

8. The apparatus of claim 6 wherein the energy emitting element comprises a resistive element.

9. The apparatus of claim 6 wherein the energy emitting element comprises a piercing tip.

10. A method for selectively heating a region of a prostate, the method comprising:

inserting an energy emitting element into a urethra, the energy emitting element having a piercing tip;

advancing the energy element through the urethra to a position adjacent to the prostate;

inserting the energy emitting element into the region of the prostate between an anterior portion of the prostate, relative to the urethra, and a lateral portion of the prostate, relative to the urethra; and

energizing the energy emitting element to heat the region of the prostate surrounding the energy emitting element.

11. The method of claim 10 wherein the steps of inserting and advancing comprise:

inserting into the urethra a catheter having an insertion end and a pathway extending along a length of the catheter, the pathway configured to provide an access to the prostate near the insertion end of the catheter.

inserting the energy emitting element into the pathway; and

advancing the energy emitting element through the pathway to the prostate.

12. The method of claim 10 wherein the step of inserting comprises inserting a microwave antenna.

13. The method of claim 10 wherein the step of inserting comprises inserting a resistive element.

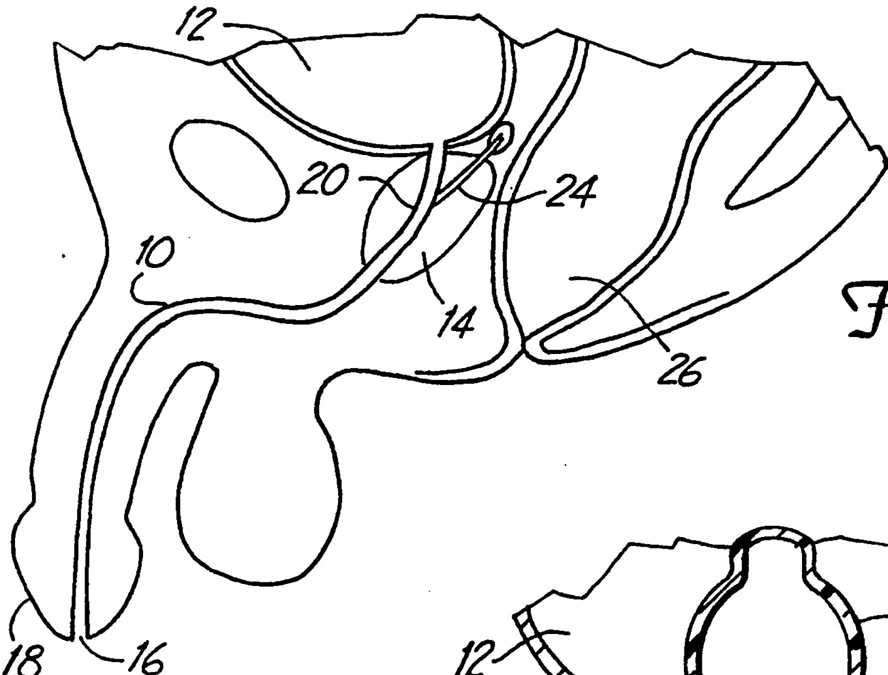

Fig. 1

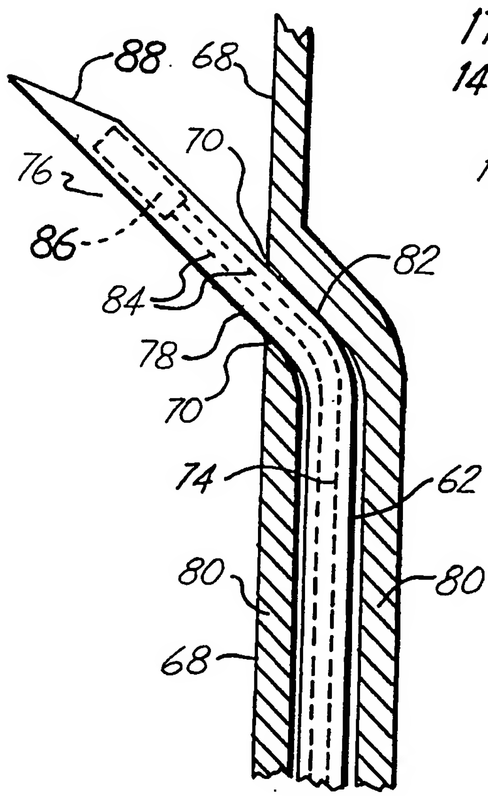

Fig. 3

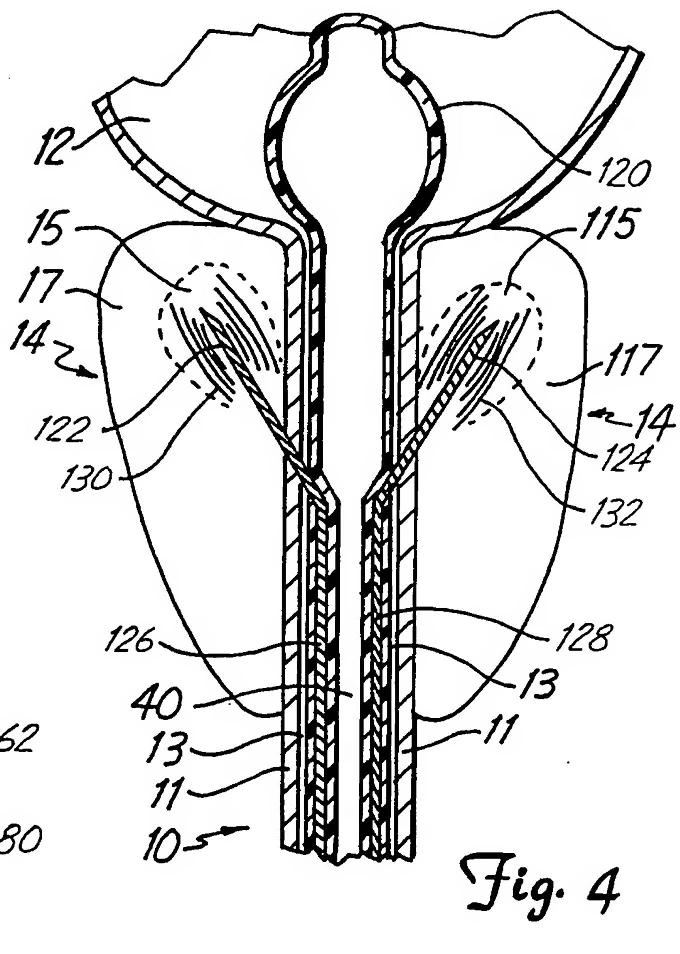

Fig. 4

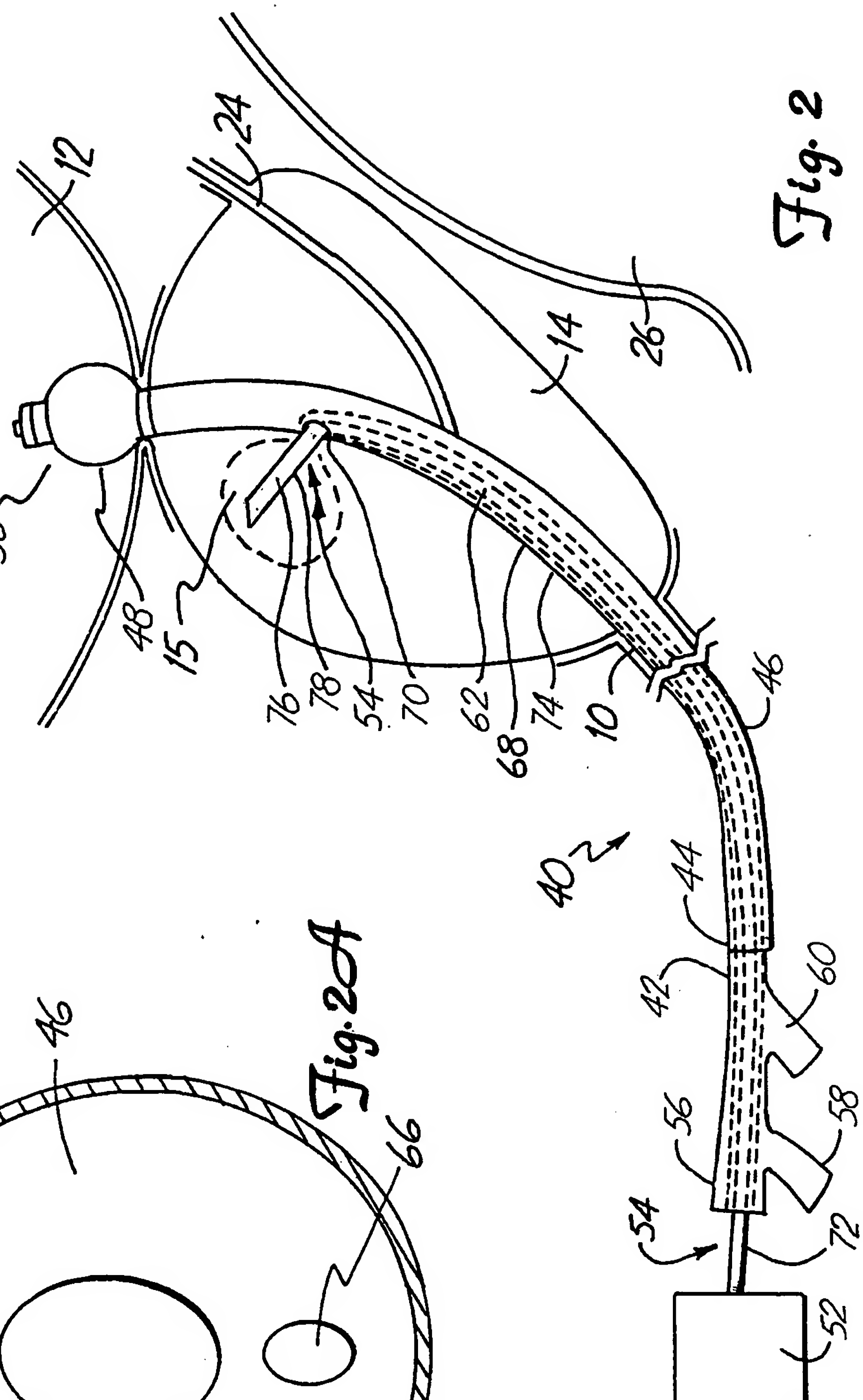
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Fig. 2

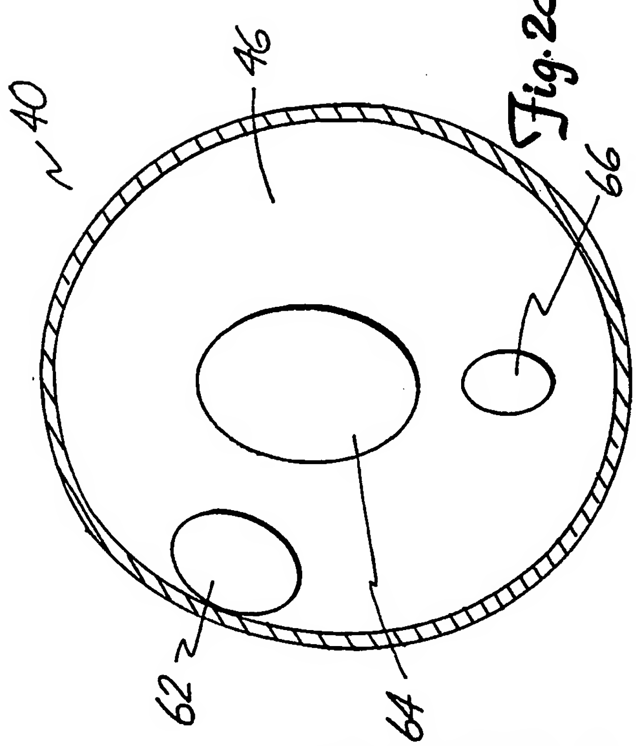
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Fig. 2A

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/11162

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61F 7/12
US CL :607/97
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604-96, 113; 606/27, 28, 31-33; 607/97, 98, 101

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	WO, A, 92/10142; (JOSHUA MAKOWER), 25 June 1992. See entire document.	1, 2, 5, 6, 9-11 --- 3, 4, 7, 8, 12, 13
Y	US, A, 4,907,589, (COSMAN), 13 March1990. See various heating means.	3, 4, 7, 8, 12, 13
Y	US, A, 4,967,765, (TURNER ET AL.), 06 November 1990. See various heating means.	3, 4, 7, 8, 12, 13

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
05 NOVEMBER 1994	20 DEC 1994

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